March 29, 2019

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
200 Independence Avenue, S.W., Room 736E
Attn: Alicia Richmond Scott, Task Force Designated Federal Officer
Washington, DC 20201

Re: **Docket Number: HHS-OS-2018-0027: Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations**

Dear Members of the Pain Management Task Force:

Thank you for the opportunity to comment on the Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations, published in the Federal Register on December 31, 2018. We commend the Pain Management Task Force (Task Force) for proposing a range of recommendations that address the current gaps and inconsistences in acute pain management, particularly in the perioperative space. As clinicians who treat surgical patients every day, we share your strong commitment to addressing the opioid epidemic and reducing rates of opioid addiction.

Unfortunately, the vast majority of surgical patients in the United States are prescribed opioids to manage their postsurgical pain[1], which is linked to persistent opioid use[2] many months after the procedure. Overprescribing of opioids has far-reaching consequences; not only is it dangerous for the patient but overprescribing also increases the likelihood of opioid diversion and misuse in our homes and communities.

We would like to provide our strong support for the recommendations from the Draft Report that we believe will be most impactful on driving system-wide change. If adopted by providers and payers, we believe they could improve patient outcomes and care, and put patients in charge of their health care decisions, including how they choose to manage their postsurgical pain.

<u>Recommendations to Align Incentives</u>

- ✓ **Use of non-opioid medications with nonpharmacologic treatments should be used as first-line therapy whenever possible in the in-patient and outpatient settings (Section 2.2 Recommendation 2a)**
    - While opioids are, in most cases, cheaper than non-opioid therapies, their use can lead to significant system expenses resulting from longer hospital stays, opioid adverse events such as nausea and vomiting, and in many cases, costs associated with opioid

[1] Kessler ER, Shah M, Gruschkus SK, Raju A. Cost and quality implications of opioid-based postsurgical pain control using administrative claims data from a large health system: opioid-related adverse events and their impact on clinical and economic outcomes. Pharmacotherapy. 2013;33(4):383-391.
[2] Carroll I, Barelka P, Wang CKM, et al. A pilot cohort study of the determinants of longitudinal opioid use after surgery. Anesth Analg. 2012;115(3):694-702.

addiction.[3] Using non-opioid therapies to manage acute pain perioperatively, has been proven to be effective and significantly eliminate/reduce opioid associated downstream adverse events[4].

- ✓ **Appropriate reimbursement and authorization policies for multimodal approaches… (Section Recommendation 1c) and the Centers for Medicare & Medicaid Services (CMS) and payors should provide reimbursement that aligns with the medication guidelines that the Task Force has described. (Section 2.2 Recommendation 2e):**
    - There are already several FDA-approved non-opioid therapies on the market to treat postsurgical pain, and potentially more that will soon become available in the marketplace. Unfortunately, current reimbursement policies hinder patient and provider access to those therapies. For example, FDA-approved non-opioids like liposomal bupivacaine and intravenous acetaminophen can be utilized to manage acute pain perioperatively.[5,6] However, many hospitals struggle with the financial barriers due to lack of separate reimbursement from payors, to the point where they block clinician access to these therapies for fear of many unreimbursed expenses. These non-opioids combined with a multimodal approach to manage patient's pain before, during, after surgery can reduce—and in some cases eliminate—the need for opioid prescribing postoperatively and should be fully reimbursable so that hospitals do not default to opioids.

<u>Recommendations to Standardize Clinical Tools and Resources</u>

- ✓ **Procedure-specific, multimodal regimens when indicated in the perioperative period, including various non-opioid medications… (Section 2.1.1 Recommendation 1a)**
    - Currently, there is a lack of standardization of procedure-specific multimodal regimens because clinicians often develop such multimodal therapies in-house and they vary by hospital depending on what medications a clinician has access to. This can often inhibit patient access issues to non-opioid therapies because of inconsistency in subsequent outcomes. Standardized, procedure-specific, multimodal regimens will lead to clinical practice that is more easily studied and replicated, helping to generate the data necessary (e.g., decreased length of stay, lower costs, etc.) to facilitate an uptake in multimodal therapies to manage patients' acute pain.

- ✓ **Multidisciplinary and multimodal regimens for perioperative pain control such as Enhanced Recovery After Surgery (ERAS)... (Section 2.1.1 Recommendation 1b)**

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[3] Oderda GM et al. Cost of Opioid-Related Adverse Drug Events in Surgical Patients. Journal of Pain and Symptom Management. Vol 25. No. 3 March 2003.

[4] Yu, S. Pain Control and Functional Milestones in Total Knee Arthoplasty: Liposomal Bupivacaine versus Femoral Nerve Block. Clin. Orthop Relat Res 2017 Jan; 475 (1) 110-117.

[5] Emerson et. al. Comparison of Local Infiltration Analgesia to Bupivacaine Wound Infiltration as a Part of a Multimodal Pain Program in Total Hip Replacement. Journal of Surgical Orthopaedic Advances. Vol 24 No 4. Winter 2015

[6] Sin B, et al. The Use of Intravenous Acetaminophen for Acute Pain in the Emergency Department. Acade Emerg Med 2016 May 23(5): 543-53

- Several studies support the ability of an ERAS protocol to reduce opioid consumption post-surgery.[7,8] Most recently, the American College of Surgeons released data showing a 60 percent reduction in opioid use during a patients' stay in the hospital following the implementation of an ERAS protocol in bariatric surgery.[4]

✓ **Development of acute pain management guidelines for common surgical procedures… (Section 2.1.1 Recommendation 2a)**

- Existing data supports the Task Force's recommendation to develop and optimize acute pain management guidelines. These guidelines could prevent long-term chronic pain, which poses a significant economic burden for health systems and societies.[9]

✓ **Establish an online resource of evidence-informed educational materials for common pain conditions and appropriate treatment modalities (Section 3.2.1 Recommendation 3a)**

- Conversely, it is important that one-on-one education with the patient occurs prior to a surgical procedure. Surgeons are well-placed to play a strong role in reducing opioid addiction and subsequent opioid-related deaths through education.[10] Many patients are unaware that there are non-opioid options to manage their acute pain perioperatively. Studies strongly support that preoperative opioid and pain management counseling results in a significant decrease in overall opioid consumption after surgery. For example, one such study showed that 90 percent of patients who received oral and written forms of patient communication about pain, the negative effects of opioids, and non-opioids ultimately declined their post-surgical opioid prescription and utilized other methods to manage their pain.[11]

We are dedicated to being a part of the solution and we applaud the Task Force for its work to date to support our efforts. We believe the Task Force's recommendations are a great step in closing the opioid addiction "gateway" that surgery poses.

We appreciate the opportunity to provide feedback and applaud the Task Force in undertaking this effort and look forward to supporting the implementation of the final recommendations.

Sincerely,

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[7] Rojas, KE. et al. A pilot study of breast surgery Enhanced Recovery After Surgery (ERAS) protocol to eliminate narcotic prescription at discharge. Breast Cancer. Res. Treat. 2018 Oct; 171 (3): 621-626.
[8] Pearl M., A Lloyd, and K. Higa. ERABS leads to reduced opioid use among bariatric surgery patients. ACS Bulletin. Retrieved from: http://bulletin.facs.org/2019/01/erabs-leads-to-reduced-opioid-use-among-bariatric-surgery-patients/
[9] Joshi GP et al. Best Pract Res Clin Anaesthesiol. 2014; 28:191-201.
[10] Scarlet, S. et. al. Preoperative communication promotes opioid stewardship. American College of Surgeons Bulletin. Retrieved from: http://bulletin.facs.org/2017/08/preoperative-communication-promotes-opioid-stewardship/ (January 7, 2019)
[11] Sugai, DY, et al. The Importance of Communication in the Management of Postoperative Pain. Hawaii Journal of Medicine & Public Health 2013. Jun; 72(6): 180-184.

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